

to the field illuminator 40 by means of a recognizable feature (e.g. a notch in the container 18), such that once the field illuminator 40 locates the recognizable feature, all other features within the chamber 20 can be accessed by virtue of their coordinate address (i.e., known spatial location). In a simplistic embodiment, the positioner 86 might include a pair of thumb wheels 5 geared to a tray 87 (or to the field illuminator 40), such that the tray 87 (or the field illuminator 40) can be moved in a plane by rotating the thumb wheels, in a manner similar to that of a microscope stage. In a second embodiment, the positioner 86 includes electromechanical actuators 98 for moving the disposable container 18 in the plane (e.g., the x-y plane) relative to the imaged field (or vice versa). The actuators 98 may be any electromechanical device that can accurately and repeatably position the container 18 and hold that position until directed otherwise. For those analyses that require mixing of the biologic sample and a reagent, the actuators 98 may also be capable of moving the container 18 in a manner that causes the sample and reagent to mix within the reservoir 22.

III. The Programmable Analyzer

Referring to FIGS. 1 and 4, as stated earlier, the Programmable Analyzer 16 is described herein as a stand alone device that is in communication with the Reader Module 12 and the Sample Transport Module 14. The Programmable Analyzer 16 could, alternatively, be packaged with the Reader Module 12 and Sample Transport Module 14 in a single device.

The Programmable Analyzer includes a central processing unit (CPU) and hardware connecting the Reader Module 12, Sample Transport Module 14, and the Programmable Analyzer 16 together. Software programmed into the CPU (or remotely accessible by the CPU) provides instruction sets, hereinafter referred to as analysis algorithms, that detail all the steps necessary to perform a variety of analyses. Simplistic instruction sets may alternatively be provided directly to the Programmable Analyzer 16 through the container label 28 and label reader 38. The Programmable Analyzer 16 preferably further includes a keyboard/keypad type input device 100 and a monitor type display device 102. A variety of acceptable keyboards/keypads and monitors are commercially available and therefore will not

be described further. The CPU is programmed to control the Reader Module 12 and the Sample Transport Module 14, directing them to perform tasks according to the analysis algorithm at hand. The CPU is also programmed to receive and manipulate the electronic data format of the fluid sample image (referred to hereinafter generally as "data") produced by the 5 image dissector 42. The analysis algorithms and/or input from the operator and/or container label 28 provide the instructions for manipulating the data into a useful output.

The CPU's programming reflects the apparatus's 10 level of automation. In the case of the simplistic embodiment of the positioner 86, no positioner programming is provided because manually operated thumb wheels are used in lieu of automation. Likewise, the mechanism 84 for transferring biologic sample from the container reservoir 22 to the container chamber 20 may also be manually operated. In an automated embodiment, programming stored within the CPU or remotely accessed by the CPU (and/or input from the keyboard 100) enables the CPU, for example, to control the label reader 38 to extract information from the container label 28, to transfer biologic sample from the container reservoir 22 to the container chamber 20, and to control movement of the container 18 relative to the Reader 15 Module 12 (or vice versa).

The It is the analysis algorithms programmed into the CPU that help give the present invention apparatus its versatility and ability to perform analyses in a variety of disciplines. The algorithms are constructed to utilize the features of the container 18 as well as the 20 capabilities of the apparatus 10 such as the Reader Module's 12 ability to determine the volume of one or more select sample fields and the Sample Transport Module's 14 ability to move the container 18 to permit access to any sample field. As a general overview of how such algorithms would work, when the container 18 is loaded into the apparatus 10, the container label 28 is read thereby providing the Programmable Analyzer 16 sufficient 25 information to determine what test(s) is requested and the information necessary to perform that test. The Programmable Analyzer 16 is programmed to use the label information to access the appropriate analysis algorithm and in some instances data files stored within the

Analyzer 16 (or stored remotely) as well. The analysis algorithm, in turn, provides the step by step instructions necessary to direct the Sample Transport Module 14 and the Reader Module 12, and any other functions necessary in the performance of the test.

The instructions may direct the Reader Module 12 to actuate the container valve 26
5 thereby transferring the fluid sample from the reservoir 22 to the chamber 20. For those analyses that are timed, the valve actuation may be used to initiate the time period. The Reader Module 12 may also be used to visually monitor the chamber 20 to determine if or when an optimum quantity of sample has reached the chamber 20. The instructions can also direct the Reader Module 12, based on information provided through the container label 28, to 10 use particular filters 58,66 appropriate for particular wavelengths, or to move the container 18 to particular positions to provide the Reader Module 12 access to particular fields, etc. When the test at hand calls for a chemical measurement, for example, the analytical algorithm identified through the label 28 will call for the measurements necessary to determine the optical density of the field. The concentration of the analyte can subsequently be calculated 15 by the Programmable Analyzer 16 using an analysis algorithm ~~which that~~ uses calibration data communicated through the container label 28. For hematology analyses, on the other hand, an analysis algorithm may direct that a field be searched for images of a particular cell type for enumeration or evaluation purposes. The algorithm may direct that ~~the~~ a single, most optimal field be considered, or most preferably that multiple fields be considered and the results be 20 statistically analyzed to obtain a final statistically acceptable result. At one or more points during the analyses, the volume of the sample field may be determined, if required for the analysis, and that data used in the final results calculation .

As stated above, the considerable utility of the apparatus 10 enables a wide variety of analyses to be performed of a single sample, using a single analytical container 18. The 25 detailed examples given below are offered so that a complete appreciation of the present invention apparatus may be gained.